K111351

SEP 2 9 2011

SECTION 5

510(K) SUMMARY

US Infusion Inc dba Truecare Biomedix
2003 NW 79th Ave
Miami, FL 33122
USA

FDA CDRH DMC
MAY 13 2011
Received

Date Submitted: February 1, 2011

Submitted By: US Infusion Inc dba Truecare Biomedix USA
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US Infusion Inc dba Truecare Biomedix
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Common Name of Device: Intravascular Administration Set

Predicate Device: Vitalcare 3 In 1 Tubing (K050906)

Panel: General Hospital and Personal Use

Product Code: FPA

Device Classification: II

Name & Model Numbers of Devices.

1. TCBINF001, Intravascular administration set
2. TCBINF002, Intravascular administration set with 0.2 micron filter
3. TCBINF003, Intravascular administration set with flow regulator
4. TCBINF004, Intravascular administration set with flow regulator, 0.2 micron filter
5. TCBEXT001, Minibore extension set

Other Model Numbers and configurations may be assembled per customer request

Device Classification

a. Set, Administration, Intravascular
b. FPA
c. 21CFR880.5440
d. Device Classification II

Indications For Use

Truecare Biomedix Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Truecare Biomedix infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

Design Features

US Infusion Inc dba Truecare Biomedix Intravascular administration/extension set is sterile/pyrogen free, non-DEHP PVC tubing with the following combination of components.

a. Universal Spike. Universal spike is constructed from ABS material and has a hydrophobic vent for transfer of fluids from closed containers such as infusion bottles. The spike dimensions are variable to deliver fluid at 10, 15, 20 and 60 drops per ml. Alternatively, the spike may have a luer lock at one end which connects to non-DEHP tubing for the purposes of transporting intravenous fluids from a vial to the patient.
b. Drip chamber with 15 micron filter. The drip chamber is constructed from non-DEHP PVC or EVA, is flexible and has inbuilt 15 micron particulate disc filter which filters solution passing through it.
c. Non-DEHP PVC tubing. Variable length non-DEHP PVC tubing with differing ID/OD combinations to ensure tubing performance. Extension tubing shall have ID/OD combinations of 0.03"/0.05" (minibore), 0.01"/0.03" (microbore), various lengths; 7" to 60". Infusion tubing shall have ID of 0.1" and OD of 0.125". Various combinations of the above tubing shall be designed to deliver desired performance.

d. Flow Regulator. A commercially available dial type flow regulator may be incorporated in-line to control the flow rate of infusion fluids. The flow regulator will provide standard graduations of 5ml/hr to a maximum of 250ml/hr. The flow regulator shall be constructed from medical grade ABS and medical grade silicone disc. Optionally, a rate restricted tubing may be also incorporated in the infusion set whereby the ID and length of the tubing has been calibrated to provide a specific flow rate at gravity pressure from liquid height of 36-40"
e. Roller clamp. A roller clamp may be inserted in combination with the above components to control flow rate or to turn fluid flow on and off. Roller clamp shall be constructed from medical grade ABS plastic
f. Slide clamp.. A slide clamp may be inserted in combination with the above components to turn the fluid flow on and off. Slide clamp shall be constructed from medical grade ABS material.
g. Luer locks. Female luer locks and male luer locks may be a part of the infusion set as required and shall be constructed from medical grade ABS or non-DEHP hard PVC or medical grade PP.
h. Filters. In-line air eliminating filters may be incorporated into the infusion tubing. These filters will have pore size of 0.2 micron or 1.2 micron and shall be constructed from medical grade PVC or medical grade ABS and cellulose acetate membrane.
i. Latex free "Y" site or pre-approved needleless "Y" site for secondary infusions or medication administration. The "Y" site shall be integrated in combination with the above components and shall be constructed from hard PVC or PP or ABS (all components are medical grade). In case of latex free "injection port", the material shall be medical grade silicone.

Specification & Dimensions

US Infusion Inc dba Truecare Biomedix Intravascular Administration Set will have the following dimensional specifications:

a. Infusion tubing OD = 4.1mm, ID = 3.0mm (approximately)
b. Extension tubing regular bore OD = 2.7mm, ID = 1.6mm (approximately)
c. Extension tubing minibore OD = 2.0mm, ID = 1.0mm (approximately)
d. Extension tubing microbore OD = 1.6mm, ID = 0.6mm (approximately)
e. Additional custom dimensions may be manufactured for customers
f. Length may vary from 5" for extension set to 105" for primary infusion set

Materials
Acrylonitrile Butadiene Styrene
Non-DEHP Poly Vinyl Chloride
Polypropylene
Silicone

Substantial Equivalence:

US Infusion Inc dba Truecare Biomedix Intravascular Administration Set is substantially equivalent to the predicate device, Vitalcare 3 In 1 Intravascular Infusion Set. The component materials, indication for use, and SAL are substantially equivalent and present no additional safety concerns as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Aaron Compton
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SEP 29 2011

Re: K111351
Trade/Device Name: Truecare Biomedix Intravascular Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: September 9, 2011
Received: September 9, 2011

Dear Mr. Compton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111351

Device Name: Truecare Biomedix Intravascular Administration Set

Indications For Use: Truecare Biomedix Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Truecare Biomedix infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K111351 Richard C. Chapman 9/28/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111351